



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

d19766

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6700

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: 29-51306

August 7, 1998

Gerard Koetsier  
Oakview Dairy  
6626 Avenue 228  
Tulare, California 93274-9717

**WARNING LETTER**

Dear Mr. Koetsier:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 17 and 21, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On May 4, 1998, you sold a cow (identified by USDA laboratory report number 265911) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this cow revealed tetracycline in the kidney at 15.00 parts per million (ppm), and in the muscle at 2.20 ppm. The tolerance level for tetracycline for the edible tissues of cows has been established at 12.00 ppm in the kidney, and in the muscle at 2.00 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug RXV Tetracycline Hydrochloride Soluble Powder 324 brand of tetracycline soluble powder that your establishment uses on lactating dairy cows is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Your practice of using the Tetracycline 324 Powder brand tetracycline for treating lactating dairy cows does not conform to labeling instructions. Product labeling states that it is to be administered in the drinking water of calves for the treatment of scours and pneumonia. Using the Tetracycline 324 Powder to prepare a uterine bolus for use in your cattle is an unapproved use for which safety and efficacy have not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Failure to comply with the label instructions on the drugs you use to treat your cows presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

Oakview Dairy  
Tulare, California

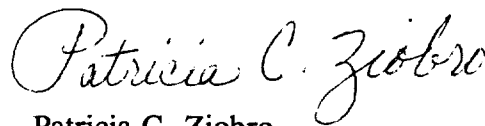
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You should be aware that it is not necessary for you to have personally shipped an adulterated dairy cow in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated dairy cow for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, CSO, 2202 Monterey Avenue, Suite 104E, Fresno, California, 93721.

Sincerely yours,



Patricia C. Ziobro  
District Director  
San Francisco District

cc:

